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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,010	05/02/2001	Ioana M. RizoIU	BI9485P	5692

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STOUT, UXA, BUYAN & MULLINS LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

EXAMINER

SHAY, DAVID M

ART UNIT PAPER NUMBER

3739

DATE MAILED: 11/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.



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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on July 25, 2003
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-4, 6-15, 17-21, 23-35, & 37-120 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-4, 6-15, 17-21, 23-35, & 37-120 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s): _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

With respect to the argument regarding the drawing objection, the examiner notes that the term "ball rollers" indicates balls that roll. There is nothing in figure 24 or any other originally submitted figure that depicts a ball capable of rolling. There is also no illustration depicting any transparent material. Regarding the enablement rejection the qualification that the arms "glide" excludes the embodiment with balls that "roll".

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 29-32, 37, 38, 48-59, and 77-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rizoïu et al (WO '928) in combination with Vassiliadis et al. Rizoïu et al (WO '928) provide the teachings set forth above and additionally teach the use of the electromagnetically induced mechanical cutter in conjunction with a variety of conventional tools including lasers (see page 47, line 22 through page 55, line 21). Vassiliadis et al teach that irradiating a tooth at low levels can desensitize the tooth and enable more rapid removal of dentin by conventional laser means (see column 5, line 7-30) and to employ the cutting laser when the water is not being sprayed (see column 6, lines 5-14) and that tissue can be removed bloodlessly. It would have been obvious to the artisan of ordinary skill to employ the laser steps of Vassiliadis wherein tissue is removed quickly by thermal cutting in the method of Rizoïu et al (WO '928), since this would provide rapid tissue removal for a large amount of tissues, while enabling the thermally damaged tissue remaining to be removed by the non-thermal cutting of Rizoïu et al (WO '928), since this would save time and be less stressful on the patient, as taught by Vassiliadis et al or to employ the non thermal cutting steps of Rizoïu et al (WO '928) in the

method of Vassiliadis et al, since this would leave only healthy, viable tissue with a good bonding surface, as taught by Rizoïu et al (WO '928) thus producing a method such as claimed.

Claims 33-35, 60-76, 99-109, and 111-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rizoïu et al (WO '928) in combination with Rizoïu et al (1994 "The Efficiency...") and Sharon et al. Rizoïu et al (WO '928) teach a device as claimed except for the leg (please note all structures predicated on the contacting leg e.g. the shape thereof) are also not taught. Rizoïu et al (1994 "The Efficiency...") teach that the effect desired by Rizoïu et al (WO '928) requires that a certain distance be maintained between the fiber end and the tissue surface or no ablation will occur (see the paragraph bridging pages 110 and 111). Sharon et al teach the use of a variety of contacting devices to maintain an appropriate distance between the laser emission end of an applicator and the tissue surface (see figures 1-11) wherein the coupling is considered part of the housing. Thus it would have been obvious to the artisan of ordinary skill to employ the single legged, double legged, or transparent members of Sharon et al, since these are useful for maintaining the device an appropriate distance from the tissue, as taught by Sharon et al in the device of Rizoïu et al (WO '928) since maintaining the distance is important to produce ablation, as taught by Rizoïu et al (1994 "The Efficiency,"); to employ a plurality of contact legs, since this is not critical, provides no unexpected result, and enables the excess water and removed tissue to be removed, which is desirable as taught by Rizoïu et al (WO '928) and to provide transparent legs, since the transparency of the legs does not in any way impede this function; to form the transparent portions from plastic, since this is not critical, provides no unexpected result, and plastics are notorious as transparent materials, official notice which has

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already been taken; and to employ soft water, since this has less contaminants than hard water, thus producing a device such as claimed.

Claims 1-4, 8, 10-15, 17-21, 23-28, 39-47, 90-98, and 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rizoiu et al (WO '928) in combination with Rizoiu et al (1994 "The Effect...") and Sharon as applied to claims 33-35, 60-76, 99-109, and 111-120) above, and further in view of Fuller et al. Fuller et al teach the use of a roller ball and the use of a lubricating solution (see Figure 2-7 and column 4, lines 30-65). It would have been obvious to the artisan of ordinary skill to employ a ball roller with a lubricant as the skin contacting portion, since sliding friction can be problematic: to use a 5 mm distance, since this is within the range taught by Rizoiu et al (1994 "The Effect...") as required for producing the effect of Rizoiu et al (WO '928) and to provide a rectangular edge or cylindrical shape since this is not critical, provides no unexpected result and are equivalent to the configurations of Sharon et al as they function in substantially the same way, thus producing a device such as claimed.

Claims 6, 7, and 9 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Rizoiu et al (WO '928) in combination with Rizoiu et al (1994 "The Effect..."), Sharon et al, and Fuller et al as applied to claims 1-4, 8, 10-15, 17-21, 23-28, 39-47, 90-98 and 110 above, and further in view of Itzkan. Itzkan teaches routing the fluid delivery and suction lines through the support leg of a distance member. It would have been obvious to the artisan of ordinary skill to route the fluid lines through the contact member, since this is adjacent the contact area which is where the moisture is desired to be situated to produce the effect described by Rizoiu et al (WO '928), as taught by Rizoiu et al (1994 "The Efficient...") thus producing a device such as claimed.

Regarding applicant's arguments directed to the rejection under 35 USC 112, first paragraph, these have been considered, but are not convincing. The passage at page 27 has been reviewed, but does not support the claim language. The cited passage discusses using smooth or rounded ends on the contact arm, notes in passing that ball rollers may be used then notes that the device can put out an additive with lubricating properties to allow the contact arm to glide across the surface. As the ball rollers would roll there would be no need for lubrication to allow them to glide. Thus the rejection under 35 USC 112, first paragraph is hereby repeated.

Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure is silent on lubricating a ball roller.

Applicant argues that ' "absorption" should have its common meaning which is consistent with the wording of the instant application'. While the examiner notes that absorption should be given its common meaning, the problem lies in reconciling this with the wording of the instant application. Please note that the instant application includes the wording "This application is a continuation in part of co-pending U.S. Application Number 09/298,112... the contents of both of which are expressly incorporated herein by reference." Turning now to the expressly incorporated application, now U.S. Patent 6,544,256 includes the wording "The high absorption of the electromagnetic energy, by the fluid particles, resulting in expansion of the fluid particles, is a key element of the present invention." (emphasis added, see column 9, lines 45-47) and "Additionally the amount and the properties of the atomized fluid particles may be

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varied in accordance with different areas and/or desired disruptive forces desired forces to be imparted ... (column 11, lines 42-45). Thus clearly the wording of the instant application calls for variation of the properties of the fluid (presumably including absorption) but in the context of a fluid that will still have "high absorption" as this is "a key element of the present invention" given this wording of the instant application, exactly what is intended to be encompassed by the terms "absorption"; "highly absorbed"; and "not highly absorbed" is unclear since, in order to be describing the inventions disclosed these terms must all fall within the realm of "high absorption". Thus the indefiniteness rejection based on these terms is maintained and repeated.

Claims 1-4, 6-15, 17-21, 23-35, and 37-120 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The indefiniteness involving the term "absorption" and the modification thereof is again brought to applicant's attention. While applicant's comment that "any similarity in operating parameters... may result from the fact that both applications are directed at least in part to dermatological treatment procedures" is noted, this does not alter the basic physical properties of water e.g. the extent to which various wavelengths of light are absorbed thereby) and thus the fact that all the disclosed wavelengths are specifically discussed as highly absorbed in the parent, the fact that no new fluids are recited in the instant case; and the specific recitation of high absorption as a key feature of the invention still renders the term indefinite, as it is unclear how they suddenly become "not highly absorbed" herein. Especially in view of the express requirement on page 7 lines 14-17 of the instant disclosure that the wavelength and the fluid be "properly matched (meaning it is highly absorbed)".

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Regarding the art rejections it is noted that RizoIU et al (WO '928) teach the use of the hydrokinetic cutter with thermal lasers. The thermal lasers use a second amount of moisture (e.g. none), which is less than the first amount and will contain less vasodialator, etc than the first amount.

Regarding the combination of Vassiliadis and RizoIU et al (WO '928) applicant theorizes that "it is quite possible that the WO '928 device would already, without modification, operate in a rapid pain free fashion on the tooth". While applicant's theory is noted, it is not germane to the evaluation of the propriety of the combination. As one having ordinary skill in the art is well aware, the precursor to laser tooth tissue removal was mechanical removal, which was painful and required some sort of anesthesia. As specifically recited in RizoIU et al (WO '928) the removal mode as also mechanical. This would lead one having ordinary skill in the art to understand that some sort of anesthesia would be required.

Applicant then points to the commercial product covered by RizoIU et al (WO '928), asserting that "one skilled in the art would be aware of the product...which was known at the time of the invention to operate without inducing substantial pain on teeth, (See www.biolase.com). The examiner firstly notes that it is the RizoIU et al (WO '928) document, which has been applied to the claims, not the product developed therefrom. This notwithstanding, the examiner has perused the cited web site and has located two articles (attached). "Lasers for Every Dentist" extols the virtues of the product referring to it as "pain-free" and the section on "Endo/Root Canal Procedures" includes the quote "I don't use any anesthesia" from Dr. James Jesse. The second article ("Complete root canal therapy using the Waterlase YSGG all -tissue dental laser") which describes itself as containing "step-by-step

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procedures for using the Waterlase YSGG all – tissue dental laser ... to complete Endolase root canal therapy.” Note step 1: “ use the 600 μ m endo laser tip with very little laser energy to desensitize the tooth.” Thus applicant’s assertions that such a no water procedure (i.e. low level laser tooth desensitization, which is clearly not considered “anesthesia” in the art, as can be seen from the above passages) would not be used are not convincing.

The remainder of applicant’s arguments, merely listing the references and a summary of the claim limitations followed by the assertion that the references do not disclose or suggest the limitations with no indication of specifically what is lacking in the combination are not convincing. With respect to Fuller et al, applicant argues that Fuller et al teach away from the claimed interaction zone placement. This has no bearing on the use of a ball roller for tissue contacting to provide proper spacing, the main teaching for which Fuller et al is relied upon. Thus this argument is not convincing.

Applicant's arguments filed July 25, 2003 have been fully considered but they are not persuasive. The arguments are not convincing for the reasons set forth above.

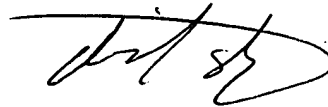
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to David Shay at telephone number 308-2215.

A handwritten signature in black ink, appearing to read 'David M. Shay', with a stylized flourish at the end.

Shay/DI

October 24, 2003

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330